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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,985

10/28/2005

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EXAMINER

WOOD, AMANDA P

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,985	Applicant(s) NODA ET AL.	
	Examiner Amanda P. Wood	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/05</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-7 are presented for consideration on the merits.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of JAPAN 2002-259475 (filed on 09/05/2002) has been received with the present application's 371 papers. Acknowledgment is made of the present application's status as a 371 case for the application PCT/JP03/10946, filed on 08/28/2003.

Claim Objections

Claims 1 and 2 are objected to because of the following informalities: For clarity in the claims, steps within claims 1 and 2 should be numbered by some means other than that used to number the claims themselves (e.g., either using small Roman numerals in parenthesis, or using letters to indicate steps). Appropriate correction is required.

Claim 1 is objected to because of the following informalities: Claim 1 recites the phrase "this substrate layer" in line 9. Applicant should use either "the substrate layer" or "said substrate layer" to avoid confusion. Appropriate correction is required.

Claim 1 is objected to because of the following informalities: Claim 1 recites the phrase "by measuring image" in lines 3 and 22. This phrase appears to be missing words which would clarify the meaning of the phrase.

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 cancels claim limitations from claim 1 and replaces them with other limitations instead of further limiting claim 1. In particular, Claim 2 just places the steps of claim 1 in a different order from the original order in claim 1, therefore, claim 2 does not further limit its parent claim.

Claim 3 is objected to because of the following informalities: Claim 3 recites the phrase "to measure fluorescent image" in line 5. This phrase appears to be missing words and/or letters which would clarify the meaning of the claim.

Claim 7 is objected to because of the following informalities: Claim 3 recites the phrase "to measure fluorescent image" in line 4. This phrase appears to be missing words and/or letters which would clarify the meaning of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the adhesive layer" in line 5. There is insufficient antecedent basis for this limitation in the claim. There is no prior reference to any

adhesive layer in the claim to require the use of "the." Furthermore, Claim 1 recites the limitation "an adhesive layer" in line 7. In addition, claim 1 refers to "the adhesive layer" in lines 16 and 18 and "said adhesive layer" in lines 20-21. The combination of these phrases in the claim makes it unclear whether there is only one adhesive layer or whether there are several adhesive layers in the collection sheet, and to which limitations Applicant is referring in the claim.

Additionally, claims 2-5 and 7 all refer to "said adhesive layer" but it is unclear which adhesive layer is being referred to based upon the indefinite nature of the language in claim 1.

Claim 2 recites the limitation "said adhesive layer" in line 8. There is insufficient antecedent basis for this limitation in the claim. In claim 2, Applicant recites that the steps 1 and 2 of claim 2 should replace those of claim 1. Although such replacement of these steps deems claim 2 not further limiting of its parent claim, if it were properly further limiting, the use of the above phrase in line 8 would lack antecedent basis because there is no prior reference to any adhesive layer in claims 1 or 2 prior to step 1 (as claimed in either of claims 1 or 2).

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saika et al (6,203,900B1) in view of Manian et al (6,130,745).

A method is claimed of marking by a staining agent microorganisms or cells contained in a sample and detecting the same by measuring their images.

Saika et al beneficially teach a method of detecting microorganisms in a sample comprising contacting a pressure-sensitive adhesive sheet with the surface of a test object (i.e., a sample comprising microorganisms) to allow the capture of microorganisms in the sample on the adhesive layer of the sheet. Saika et al further teach that the adhesive sheet comprises an adhesive layer on a support. Furthermore,

Saika et al teach that the adhesive layer comprises a gel-like insoluble substance which cannot be dissolved in or eluted with water (see, for example, col. 8, lines 1-45).

Furthermore, Saika et al teach that the adhesive layer can comprise chromogenic substrates which may be fluorescent dyes which can be detected using a fluorescence microscope (see, for example, col. 10, lines 40-67). Saika et al beneficially teach that chromogenic substrates can be added to the adhesive layer either before the sheet is contacted with a sample so that microorganisms become stained once they are collected on the adhesive sheet (see, for example, col. 10, lines 40-67), and also that microorganisms can be stained prior to coming into contact with the adhesive substrate (see, for example, col. 20, lines 1-25).

Saika et al do not expressly teach a method wherein the collection sheet comprises a focusing marker for autofocusing.

Manian et al beneficially teach that assays using fluorescence to identify or enumerate a target of interest (i.e., microorganisms) are useful and can be automated to increase the throughput of an assay (i.e., the number of samples screened), but that in standard microplate fluorescent assays, detection of fluorescence on the bottom of a microplate well is not possible because it is masked by background fluorescence in the rest of the well. Manian et al beneficially teach a method of automatically focusing on a thin layer at the bottom of the well (i.e., a depth of about 30 to 150 microns) by optically sensing a reference point on a microplate (see, for example, col. 1-2). Manian et al teach that once the location of the reference surface is known, this location can be used

to relocate the beam of light onto a target layer in the microplate well if the target layer is a known relation to the reference surface (see, for example, col. 3, lines 1-47).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Saika et al based upon the beneficial teachings provided by Manian et al with respect to the art-recognized method of providing a reference point to enable automatic focusing for observation of biological cells using fluorescence imaging, as discussed above. Manian et al beneficially teaches that background fluorescence masks fluorescence in the bottom of a microplate well, and therefore, using a focusing mark for autofocusing such samples would be beneficial so as to provide a means for finding the area at the bottom of the well more quickly. Based upon Manian et al, it would have been obvious and beneficial to provide a reference marker with the adhesive sheet taught by Saika et al, since microorganisms on an adhesive sheet stained with fluorescent dye can have the same difficulty being detected as those observed by Manian et al (i.e., background fluorescence masking fluorescence in the desired layers of microbes on the adhesive layer) and would benefit from such a marker by allowing quick focusing on the target microorganisms. Therefore, one of ordinary skill in the art would have easily conceived of providing a focusing mark to focus which would be not on the same surface on which microorganisms are collected, but would be at a known distance from said surface, based upon the teachings provided by Saika et al and Manian et al. The result-effective adjustment of particular conventional working conditions (e.g., using a particular

thickness of adhesive layer) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saika et al (6,203,900B1) in view of Yahiro (US 2001/0033414 A1), as cited in the IDS filed 3/7/2005.

A method is claimed of marking by a staining agent microorganisms or cells contained in a sample and detecting the same by measuring their images.

Saika et al beneficially teach a method of detecting microorganisms in a sample comprising contacting a pressure-sensitive adhesive sheet with the surface of a test object (i.e., a sample comprising microorganisms) to allow the capture of microorganisms in the sample on the adhesive layer of the sheet. Saika et al further teach that the adhesive sheet comprises an adhesive layer on a support. Furthermore, Saika et al teach that the adhesive layer comprises a gel-like insoluble substance which cannot be dissolved in or eluted with water (see, for example, col. 8, lines 1-45).

Furthermore, Saika et al teach that the adhesive layer can comprise chromogenic substrates which may be fluorescent dyes which can be detected using a fluorescence microscope (see, for example, col. 10, lines 40-67). Saika et al beneficially teach that chromogenic substrates can be added to the adhesive layer either before the sheet is contacted with a sample so that microorganisms become stained once they are collected on the adhesive sheet (see, for example, col. 10, lines 40-67), and also that microorganisms can be stained prior to coming into contact with the adhesive substrate (see, for example, col. 20, lines 1-25).

Saika et al do not expressly teach a method wherein the collection sheet comprises a focusing marker for autofocusing.

Yahiro beneficially teaches a method for efficiently observing a biochemical substance (i.e., animal cells, bacteria, etc.) by focusing accurately and rapidly on the substance disposed on the inside of a container made of transparent materials, such as a microplate, wherein a focusing mark used as a reference when a focal point of an optical system (i.e., a microscope) is adjusted, is disposed on the outside (or inside surface) of a transparent bottom of each well in a microplate. Yahiro teaches that a focus-shift-distance corresponding to a distance between the mark and a desired position to be observed is determined and the optical system focuses on the mark, then the focal point of the optical system is shifted by the focus-shift-distance, allowing an object to be focused on accurately. Yahiro beneficially teaches that the above method is necessary because images obtained by microscopic observation of biological substances, such as animal cells and bacteria, are often pale in color and have a blurry

outline. Furthermore, Yahiro beneficially teaches that manually focusing such images takes too much time, and therefore automatic observation is necessary, but has been difficult to apply for the above reasons, without automatic focusing incorporated into the method (see, for example, Abstract and pg. 1-2).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Saika et al based upon the beneficial teachings provided by Yahiro with respect to the art-recognized method of providing a focusing mark to enable automatic focusing for observation of biological cells under an optical system, as discussed above. Yahiro beneficially teaches that biological specimen are difficult to image and detect under optical systems because of lack of color, blurry lines, and difficulty in manual focusing, and therefore, using a focusing mark for autofocusing such samples would be beneficial. Furthermore, based upon Yahiro's teachings, it would have been obvious and beneficial to combine the teachings of Saika et al, with respect to staining and capturing microorganisms for imaging so as to provide better color contrast for imaging. Therefore, one of ordinary skill in the art would have easily conceived of providing a focusing mark to focus which would be not on the same surface on which microorganisms are collected, but would be at a known distance from said surface, based upon the teachings provided by Saika et al and Yahiro. The result-effective adjustment of particular conventional working conditions (e.g., using a particular thickness of adhesive layer) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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APW
Examiner
Art Unit 1657



CHRISTOPHER R. TATE
PRIMARY EXAMINER